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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,123	08/20/2003	Nigel Gordon John Richards	UF-314XC1	7962

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,123	RICHARDS ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *10-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 7-9* is/are rejected.

7)☒ Claim(s) *2,3,5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/21/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an isolated polynucleotide and a cell transformed with said isolated polynucleotide, classified in class 435, subclass 252.3.

II. Claim 10 , drawn to a transgenic animal, classified in class 800, subclass 13.

III. Claims 11-15, and 43, drawn to a transgenic plant and method for making said transgenic plant, classified in class 800, subclass 278.

IV. Claims 16-20, 27-30, drawn to a purified oxalate decarboxylase, classified in class 435, subclass 232.

V. Claims 21-26, drawn to a method for degrading oxalate in a fluid, classified in class 435, subclass 262.

VI. Claims 31-33, drawn to a device comprising a surface that comes into contact with a fluid that may contain oxalate, classified in class 604, subclass 6.16.

VII. Claims 34 and 35, drawn to a method for detecting the presence of oxalate in a sample, classified in class 435, subclass 7.4.

VIII. Claims 36-42, drawn to a method for providing therapeutic oxalate degradation to a human or animal in need of therapy, classified in class 424, subclass 94.1.

2. The inventions are distinct, each from the other because of the following reasons:

The oxalate decarboxylase of Group IV and the polynucleotide of Group I are patentably distinct products for the following reasons. The oxalate decarboxylase of Group IV is a polypeptide that is composed of amino acids, while the polynucleotide of Group I is a nucleic acid that is composed of purine and pyrimidine units. Polypeptides and nucleic acids are known in the art to be chemically and structurally distinct molecules. While the polypeptide of Group IV can be made by recombinant techniques using the polynucleotide of Group I, the polypeptide of Group IV can be recovered from a natural source by using protein purification techniques such as affinity chromatography.

Searching the invention of Group I and Group IV together would impose a serious search burden. The search of the polypeptide of Group VI and the polynucleotide of Group I are not coextensive. The amino acid sequence of the polypeptide of Group VI is searched in the amino acid databases while the polynucleotide is searched in the nucleotide databases. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications.

There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching in the non-patent literature, therefore is not coextensive. Thus, the search for each of the inventions of Groups I and IV requires an extensive analysis of the art retrieved in a sequence search of the appropriate databases and will require an in-depth analysis of technical literature.

The oxalate decarboxylase of Group IV, transgenic animal of Group II, and the transgenic plant of Group III are patentably distinct products for the following reasons. The polypeptide of Group IV, transgenic animal of Group II, and the transgenic plant of Group III are chemically and structurally distinct entities. The polypeptide of Group IV is a molecule composed of amino acids, while the transgenic animal of Group II and the transgenic plant of Group III are living whole organisms.

Searching the invention of Groups II, III, and IV together in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches which have different limits, boundaries, scope, and subject matter. The searches for each of the inventions of Groups II, III, and IV are not coextensive. The inventions of Groups II, III, and IV have a separate status in the art as shown by their different classifications. Thus, searching the invention of Groups II, III, and IV together would impose a serious search burden.

Inventions V, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The processes of Inventions V, VII, and VIII are distinct and unrelated because they require different process steps, reagents, and parameters; have different purposes; and produce different products and/or effects. The inventions of Groups V, VII, and VIII have a separate status in the art as shown by their different classification and each requires separate and distinct searches that would be burdensome.

Inventions V, VII, and VIII are unrelated to Inventions I-III and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Inventions V, VII, and VIII do not require the products of Inventions I-III and VI.

Invention IV and Inventions (V, VII, and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the oxalate decarboxylase in a process to make antibodies to said oxalate decarboxylase. Searching the inventions of Groups IV, V, VII, and VIII together would impose a serious search burden. The inventions of Groups IV, V, VII, and VIII have a separate status in the art as shown by their different classifications. The search for each of the inventions of Groups IV, V, VII, and VIII are not coextensive since each search has different limits, boundaries, scope, and subject matter.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. During a telephone conversation with Doran R. Pace on August 3, 2004, a provisional election was made without traverse to prosecute Invention I, claims 1-9. Affirmation of this election must be made by applicants in replying to this Office action. Claims 10-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Claims 1-9, drawn to an isolated polynucleotide and a cell transformed with said isolated polynucleotide, are under consideration in this Office Action.

7.. Drawings submitted on 8/20/2003 are accepted by the Examiner.

8. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

9. The computer readable form (CRF) of the Sequence Listing dated 2/23/2004 have been received and have been processed by the Scientific and Technical Information Center (STIC).

Claim Rejections - 35 U.S.C. § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 7-9 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 7, as written, does not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105.

The claims should be amended to indicate the hand of the inventor, e.g., by insertion of the phrase "An isolated cell". Claims 8 and 9 which depend from claim 7 are also rejected because they do not correct the defect of claim 7.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is genus claim that is directed toward any isolated polynucleotide of any nucleotide sequence and structure from any species of the genus *Aspergillus* which encodes any oxalate decarboxylase of any amino acid sequence and structure. The scope of claim 1 includes many polynucleotides with widely differing structural, chemical, and physical characteristics from many species of *Aspergillus*. Furthermore, the genus is highly variable because a

significant number of structural differences between genus members is permitted.

The specification discloses polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 2 from *Aspergillus niger* which encode the *Aspergillus niger* oxalate decarboxylase. However, the specification fails to provide a written description of additional polynucleotides from other *Aspergillus* species which encode other oxalate decarboxylases as encompassed by the claimed genus. Neither the specification nor the general knowledge of those skilled in the art provide evidence of any partial structure which would be expected to be common to the members of the claimed genus. Thus, the disclosed polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 2 from *Aspergillus niger* are not representative of the claimed genus since other members of the genus have nucleotide sequences and structures that are different from the disclosed polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 2 from *Aspergillus niger*.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the necessary common features or attributes possessed by members of the genus since the disclosed human polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 2 from *Aspergillus niger* are not representative of the claimed genus. Accordingly, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 7-9 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1 and 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanner et al. (J Biol Chem. 2001 Nov 23;276(47):43627-34. Epub 2001 Aug 23; PTO 892).

Tanner et al. teach an isolated polynucleotide encoding *Bacillus subtilis* oxalate decarboxylase, *E.coli* cells transformed with said isolated polynucleotide encoding *Bacillus subtilis* oxalate decarboxylase, and frozen *E.coli* cells transformed with said isolated polynucleotide encoding *Bacillus subtilis* oxalate decarboxylase (seen entire publication

especially, p. 43628-43631 and p. 43628, left column, last paragraph). Thus, the reference teachings anticipate claims 1 and 7-9.

16. Claims 1 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Scelonge et al. (WO 9842827 A2; PTO 892).

Scelonge et al. teach an isolated polynucleotide encoding *Aspergillus phoenices* oxalate decarboxylase; plant host cells transformed with said isolated polynucleotide encoding *Aspergillus phoenices* oxalate decarboxylase; and lyophilized plant host cells transformed with said isolated polynucleotide encoding *Aspergillus phoenices* oxalate decarboxylase (see entire publication and claims, especially claims 1-11; and specification p. 2, lines 21 to p. 8, line 20, p. 13-15, and p. 16, lines 22-27). Thus, the reference teachings anticipate claims 1 and 7-9.

17. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wipat et al. (Microbiology. 1998 Jun;144 (Pt 6):1593-600, and Accession AJ223978; PTO 892) as evident by Tanner et al. (J Biol Chem. 2001 Nov 23;276(47):43627-34; PTO 892).

Wipat et al. teach that chromosomal DNA was isolated from *Bacillus subtilis*, the chromosomal DNA was fragmented and cloned into plasmid pUC18, the fragments were sequenced, and a chromosomal fragment was found to contain the *Bacillus subtilis yvrK* gene that encodes a polypeptide that is 100% identical to SEQ ID NO: 9 (see Accession AJ112978, and entire publication, especially Table 1 on p. 1596).

Although Wipat et al. does not disclose that the *Bacillus subtilis yvrK* gene encodes the *Bacillus subtilis* oxalate decarboxylase, the teachings of Tanner et al. show that the property of encoding an oxalate decarboxylase is an inherent characteristic of the *Bacillus subtilis yvrK* gene taught by Wipat et al. because Tanner et al. over expressed the *Bacillus subtilis yvrK* gene in *E.coli* and found by enzymatic assays that the *yvrK* gene encodes an oxalate decarboxylase (see the entire Tanner et al. reference, especially p. 43628-43631).

Thus, Wipat et al. anticipate claim 1 since Wipat et al. teach an isolated polynucleotide that inherently encodes the *Bacillus subtilis* oxalate decarboxylase.

Claim Rejections - 35 U.S.C. § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guan et al. (US Patent 5,643,758; PTO 892) in view of the combined teachings of Wipat et al. (Microbiology. 1998 Jun;144 (Pt 6):1593-600; PTO 892) and Tanner et al. (J Biol Chem. 2001 Nov 23;276(47):43627-34; PTO 892).

Guan et al. teach (1) bacterial, animal, or plant host cells that are transformed with an expression vector containing a polynucleotide encoding a protein fused to the *E.coli* maltose binding protein; (2) methods using said bacterial, animal, or plant host cells in the expression, isolation, and purification of the said protein fused to the *E.coli* maltose binding protein; (3) the advantage that the said methods and host cells can be used in expressing and purifying virtually any polypeptide; and (4) the successful expression, isolation, and purification of beta-galactosidase, PstI restriction endonuclease, and paramyosin using *E.coli* host cells transformed with an expression vector containing polynucleotides encoding the respective proteins (see entire patent, especially column 7, line 51 to column 20, line 40; and Examples I, II, and IV).

Claims 7 and 8 differ from the teachings of the reference only in that the bacterial, animal, or plant host cells are not transformed with a polynucleotide encoding the *Bacillus subtilis* oxalate decarboxylase.

The teachings of Wipat et al. and Tanner et al. have been stated above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Guan et al. where the polynucleotide taught by Wipat et al., which inherently encodes the *Bacillus subtilis* oxalate decarboxylase as evident by Tanner et al., is substituted for the polynucleotide encoding a protein molecule in the expression vector taught by Guan et al. to thereby make bacterial, animal, or plant host cells that are transformed with a polynucleotide that encodes the *Bacillus subtilis* oxalate decarboxylase.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to obtain a transformed host cell which can be used in the methods taught by Guan et al. for the expression, isolation, and purification of the *Bacillus subtilis* oxalate decarboxylase. Furthermore, Guan et al. teach the advantage that the methods and host cells can be used in expressing and purifying virtually any polypeptide.

One of ordinary skill in the art at the time the invention was made would have had a

reasonable expectation for success for making bacterial, animal, or plant host cells that are transformed with a polynucleotide that encodes the *Bacillus subtilis* oxalate decarboxylase because Guan et al. teach the successful expression, isolation, and purification of beta-galactosidase, PstI restriction endonuclease, and paramyosin using *E.coli* host cells transformed with an expression vector containing polynucleotides encoding the respective proteins.

20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guan et al. in view of the combined teachings of Wipat et al. and Tanner et al. as applied to claims 7 and 8 above, and further in view of Sanderson et al. (Methods Enzymol. 1991;204:248-64; PTO 892).

Sanderson et al. teach that it is important to store wild-type and mutant bacterial strains using methods which not only assures survival but also preserves the genotype and hence the phenotype of the bacterial strains, and that such storage methods include freezing which is the "simplest and most common method of storage" of bacteria for periods up to 1-2 years and lyophilization which is an "effective method for long-term preservation of many microorganisms" (see entire publication, especially pp. 248- 252).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the freezing and lyophilization methods taught by Sanderson et al. on the bacterial host cells transformed with a polynucleotide encoding the *Bacillus subtilis* oxalate decarboxylase to make lyophilized or frozen bacterial cells transformed with said polynucleotide encoding the *Bacillus subtilis* oxalate decarboxylase.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this to ensure not only the survival of bacterial strains but also the preservation of the genotype and hence the phenotype of the bacterial strains as taught by Sanderson et al. Furthermore, Sanderson et al. teach the advantages that freezing is the "simplest and most common method of storage" of bacteria for periods up to 1-2 years and that lyophilization is an "effective method for long-term preservation of many microorganisms".

Conclusion

21. No claim is allowed.

22. Claims 2, 3, 5, and 6 are objected to as being dependent upon a rejected base claim, but

would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L Fronda 9/1/2004

Christian L. Fronda
Art Unit 1652